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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/555,343

11/01/2005

Akira Kato

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4524

26111

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06/25/2008

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EXAMINER

VAKILI, ZOHREH

ART UNIT

PAPER NUMBER

1614

MAIL DATE

DELIVERY MODE

06/25/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/555,343	<b>Applicant(s)</b> KATO ET AL.	
	<b>Examiner</b> ZOHREH VAKILI	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 February 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 16-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>11/15/2005, 05/16/2007, &amp; 12/27/2007</u> .                | 6) <input type="checkbox"/> Other: _____                          |



### **DETAILED ACTION**

#### **Claims 1-23 are presented for examination.**

Applicant's response to the restriction requirement filed on February 7, 2008 is acknowledged. Accordingly, Applicants elect Group I, claims 1-15, drawn to a freeze-dried preparation comprising methylcobalamin with traverse. Applicant asserts that Group I and Group II should be rejoined and examined on their merits. Applicant is reminded that these two inventions are independent and distinct from each other. Each invention has a different design with a different mode of operation and each invention requires a different field of search. Therefore if restriction between two inventions are not required there would be a serious burden on the Examiner. Claims 1-15 are not in condition for allowance and, therefore, the claims of Group I will not be rejoined with the claims of Group II. Therefore, the restriction requirement between the two groups is still deemed proper and is made final. maintained.

Claims 16-23 are withdrawn from consideration as being directed to non-elected subject matter.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a

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foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Bouloumie et al. (US Pat. No. 6284277 B1)

Bouloumie et al. teach a freeze-dried formulation consisting of an amorphous phase and a crystalline phase, which is pharmaceutically acceptable, comprising at least one nonprotein active ingredient, characterized in that it contains mannitol and alanine (see abstract). The freeze-dried product consists of an amorphous phase and a crystalline phase the amorphous phase predominantly consists of mannitol and active ingredient (see col. 4, lines 45-48). According to another of these features, the subject of the present invention is the production of stable freeze-dried products containing a pharmaceutical active ingredient cryoprotected by an amorphous solid phase consisting completely or partially of mannitol, this amorphous phase coexisting within the freeze-dried product obtained after sublimation and drying of the frozen solution, with a crystalline phase consisting essentially of alanine (see col. 4, lines 62-67 and col. 5, lines 1-2). Other pharmaceutically acceptable excipients normally used in freeze-dried forms may be introduced into the formulation according to the present invention, such as for example buffers or acid-bases which make it possible to adjust the pH, antioxidants (col. 5, lines 10-15). The solution follows a cycle comprising freezing, then sublimation and drying adapted to the volume to be freeze-dried and to the container containing the solution. Preferably, a freezing rate close to -2.degree. C./min is chosen (see col. 6, lines 13-17). The sublimation and drying times, temperatures and pressures are adjusted according to the volumes of solution to be

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freeze-dried and the residual water content desired in the freeze-dried product. A freeze-dried product is then obtained in which the alanine exists in crystallized form, and the mannitol in a completely or partially amorphous form. The freeze-dried product may be stored at 25.degree C and even up to 40 degree C without adversely affecting the chemical and biological stability of the active ingredient which it contains (see col. 6, lines 20-29). Vitamins for example used in the formulation are thiamine, riboflavin, nicotinamide, pyridoxine, sodium panthotenate, biotin, ascorbic acid, folic acid, cyanocobalamin, cobalamide, and hydroxycobalamide (col. 7, lines 40-43). Composition of a freeze-dried to be taken up in 4 ml of water. CONSTITUENTS Unit formula in (mg) Apyrogenic alanine 72.0 mg, Apyrogenic mannitol 36.0 mg (see col. 17, Example 4).

It is known in the art that the cobalamin family comprises vitamin B12 (cyanocobalamin), hydroxocobalamin, methylcobalamin, and adenosylcobalamin, among others (see US Pub. No.20020119947 A1, page 1, paragraph 0002 ).

Consequently, the reference anticipates the claimed invention defined in claims 1-15.

### ***Conclusion***

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zohreh Vakili whose telephone number is 571-272-3099. The examiner can normally be reached on 8:30-5:00 Mon.-Fri.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Zohreh Vakili

Patent Examiner  
1614

June 19, 2008

/Ardin Marschel/  
Supervisory Patent Examiner, Art Unit 1614

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